IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CURIA IP HOLDINGS, LLC, Plaintiff, v. SALIX PHARMACEUTICALS, LTD.; SALIX PHARMACEUTICALS, INC.; BAUSCH HEALTH COMPANIES INC.; ALFASIGMA S.P.A.; ALFASIGMA USA, INC., Defendants.	Civil Action No. 21-19293 (ES) (JRA)

CURIA IP HOLDINGS, LLC'S OPENING CLAIM CONSTRUCTION BRIEF

TABLE OF CONTENTS

I. INTRODUCTION 1

II. TECHNICAL BACKGROUND 2

III. LEGAL STANDARDS 6

IV. ANALYSIS OF THE DISPUTED CLAIM TERMS 9

A. "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" in claim 1 of the '099 patent 9

1. Curia's construction of "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" as its plain and ordinary meaning is consistent with and supported by the intrinsic evidence. 9

2. Defendants' proposed construction improperly adds unfounded negative limitations. 15

3. Extrinsic evidence, while unnecessary, additionally supports Curia's construction. 17

B. "characterized by an X-Ray spectrum with characteristic 2theta values" in claim 1 of the '099 patent 18

1. The intrinsic evidence supports and is consistent with Curia's construction. 18

2. Extrinsic evidence, while unnecessary, additionally supports Curia's construction. 21

3. Defendants' proposed construction impermissibly narrows the scope of the claim. 22

V. CONCLUSION 24

TABLE OF AUTHORITIES

Page(s)

Cases

Atofina v. Great Lakes Chem. Corp.,
441 F.3d 991 (Fed. Cir. 2006).....8

Biagro Western Sales, Inc. v. Grow More, Inc.,
423 F.3d 1296 (Fed. Cir. 2005).....11

Cat Tech LLC v. TubeMaster, Inc.,
528 F.3d 871 (Fed. Cir. 2008).....6

CCS Fitness, Inc. v. Brunswick Corp.,
288 F.3d 1359 (Fed. Cir. 2002).....17

Chamberlain Group, Inc. v. Lear Corp.,
516 F.3d 1331 (Fed. Cir. 2008).....17

CVI/Beta Ventures, Inc. v. Tura LP,
112 F.3d 1146 (Fed. Cir. 1997).....7

Eisai Co. v. Glenmark Pharms., Ltd.,
C.A. No. 13-1279-LPS, 2015 WL 1228958 (D. Del. March 17, 2015).....19

Ethicon LLC v. Intuitive Surgical, Inc.,
847 Fed. Appx. 901 (Fed. Cir. 2021).....8, 15, 16

Hill-Rom Servs., Inc. v. Stryker Corp.,
755 F.3d 1367 (Fed. Cir. 2014).....7

Homeland Housewares, LLC v. Whirlpool Corp.,
865 F.3d 1372 (Fed. Cir. 2017).....7, 18

Intervet Inc. v. Merial Ltd.,
617 F.3d 1282 (Fed. Cir. 2010).....11

K-2 Corp. v. Salomon S.A.,
191 F.3d 1356 (Fed. Cir. 1999).....6

Karlin Tech. Inc. v. Surgical Dynamics, Inc.,
177 F.3d 968 (Fed. Cir. 1999).....10

Luminara Worldwide, LLC v. Liown Elecs. Co. Ltd.,
814 F.3d 1343 (Fed. Cir. 2016).....16

Markman v. Westview Instruments, Inc.,
517 U.S. 370 (1996).....1, 6, 20

Markman v. Westview Instruments, Inc.,
52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996).....7

Mars, Inc. v. H.J. Heinz Co., L.P.,
377 F.3d 1369 (Fed. Cir. 2004).....12

Merck & Co. v. Teva Pharm. USA, Inc.,
395 F.3d 1364 (Fed. Cir. 2005).....13

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005) (en banc)..... *passim*

In re Qapsule Techs., Inc.,
759 Fed. Appx. 975 (Fed. Cir. 2019).....12

In re Rambus Inc.,
694 F.3d 42 (Fed. Cir. 2012).....10

Sonoco Products Co. v. Mobil Oil Corp.,
895 F.2d 1420 (Fed. Cir. 1990).....16

V-Formation, Inc. v. Benetton Grp. SpA,
401 F.3d 1307 (Fed. Cir. 2005).....14, 24

Vitronics Corp. v. Conceptronic, Inc.,
90 F.3d 1576 (Fed. Cir. 1996).....7, 8

Other Authorities

MPEP, 8th ed., rev. 1 § 2111.03 (2003) 12

MPEP, 9th ed., rev. 10 § 211.03 (2019) 12

I. INTRODUCTION

Plaintiff Curia IP Holdings, LLC ("Curia") submits this Opening Claim Construction Brief concerning U.S. Patent No. 11,739,099 ("the '099 patent"), attached as Exhibit C to the Declaration of Dr. Jennifer Swift in Support of Curia's Claim Constructions for the '099 patent filed concurrently with this brief ("Swift Dec.").[1]

Judge Salas held a *Markman* hearing on April 27, 2023 with respect to claim terms for U.S. Patent Nos. 9,186,355 ("the '355 patent"), 10,556,915 ("the '915 patent"), 10,745,415 ("the '415 patent"), and 10,961,257 ("the '257 patent"), Exhibits Q, D, E, F, respectively. *See* D.I. 135. The Court issued its *Markman* opinion related to those patents on January 26, 2024. D.I. 210. Following the *Markman* opinion, the parties filed a stipulation and order of non-infringement of the '915, '415, and '257 patents, which the Court so ordered. D.I. 226. The '099 patent was not subject to that *Markman* opinion as the Complaint alleging infringement of the '099 patent was not filed until August 31, 2023, after the *Markman* proceedings on the other patents. Therefore, the '355 and '099 patents are still at issue (collectively, the "Patents-in-Suit") in this litigation.[2]

[1] All exhibits ("Ex.") cited herein are attached to Dr. Swift's declaration unless otherwise stated.

[2] The Patents-in-Suit derive from two patent families. The '355 patent is in one

For the reasons set forth herein, Curia respectfully submits that Curia's proposed constructions of the disputed terms of the '099 patent are consistent with the intrinsic evidence and how a person of ordinary skill in the art ("POSA") would understand the terms, while Defendants' constructions are contrary to that evidence. Thus, Curia respectfully requests that the Court adopt Curia's proposed claim constructions.

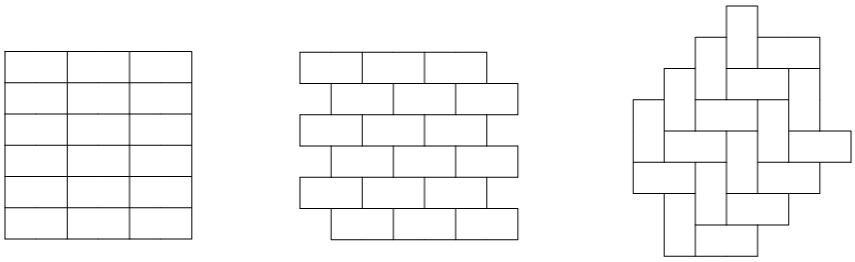
II. TECHNICAL BACKGROUND

The Patents-in-Suit disclose rifaximin polymorphic mixtures and pharmaceutical compositions comprising the same. Rifaximin is an active pharmaceutical ingredient ("API") classed as an antibiotic that can be used to treat traveler's diarrhea, hepatic encephalopathy, and irritable bowel syndrome.

Rifaximin is known to exist in numerous crystalline forms referred to as polymorphs. *See, e.g.*, Ex. C, '099 patent at 1:61-2:3 (disclosing crystalline forms α, β, γ, ε, δ, ζ, η, α dry, κ, and θ of rifaximin). Polymorphs of a compound have the same chemical composition but have different 3-dimensional packing arrangements. Swift Dec. at ¶ 43. If each of the three patterns of rectangles below were to represent

patent family with its own specification. The '099 patent belongs to a second patent family that also includes the '915, '415, and '257 patents (collectively, "the '915 patent family") and shares a common specification with those patents. Citations made to portions of any of the '099, '915, '415, or '257 patent specifications herein shall include all identical portions in the related specifications of the '099, '915, '415 and '257 patents.

an API molecule, assuming the two-dimensional patterns are reproduced in the third dimension, these would be referred to as polymorphs. *Id.*



Because different polymorphic forms of an API typically exhibit different chemical and physical properties, pharmaceutical manufacturers often wish to characterize the crystalline form(s) of an API structurally and physically. *Id.* at ¶ 45. The Food and Drug Administration ("FDA") emphasizes the importance of the characterization of polymorphs before approving a new drug application. *See id.* Specifically, the FDA teaches that "polymorphism can affect the quality, safety, and efficacy of the drug product" and that "issues relating to polymorphic forms may be relevant to new drug applications (NDAs) . . . ." *Id.*

X-ray diffraction ("XRD") is the primary method for characterizing the structure of crystalline APIs. *Id.* at ¶¶ 49-50. The diffraction pattern of a crystalline form (such as a polymorph) is unique to that particular form. *See id.* at ¶ 49. Thus, diffraction patterns can be used to distinguish one polymorph from another polymorph of the same compound.

When an X-ray beam is directed onto a sample containing polymorphs, the polymorphs diffract the X-rays in a pattern characteristic of each polymorph's

structure. *See id.* at ¶¶ 51-52. A diffraction pattern, referred to as a diffractogram, plots intensity of the diffracted X-rays against the angle of the detector ("2θ") from the incident X-ray beam. *Id.* at ¶¶ 51, 54. The positions or 2θ angles of the peaks are plotted on the x-axis, and the intensities of the peaks are plotted on the y-axis. *Id.* at ¶ 54. A sample diffractogram is shown below:

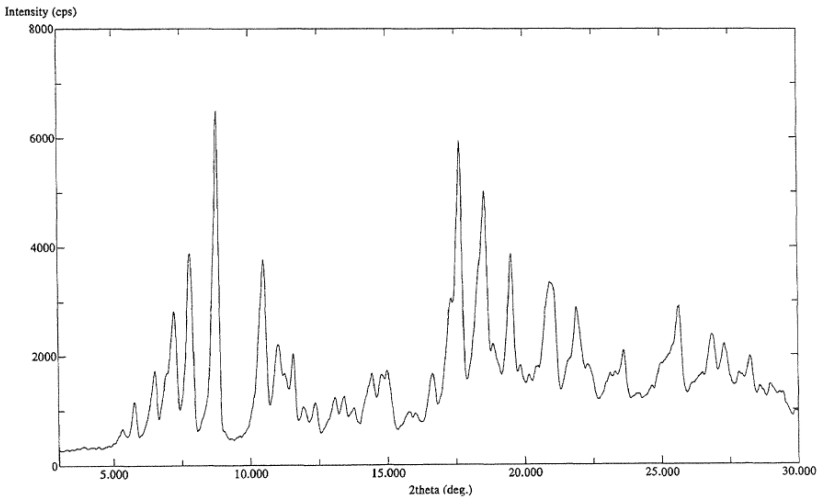


FIGURE 4

Ex. C, '099 patent at Figure 4. The tallest point of each peak is the position of the peak, and the height of the peak is its intensity. Peak positions are governed by the size and shape of the unit cell of the polymorph. Swift Dec. at ¶ 56. Relative peak intensities depend on the crystallographic unit cell content (nature and positions of atoms within the crystal lattice) of the polymorph. *See generally* Ex. K, 37 United States Pharmacopeia ("USP") <941> (2014) ("USP 941"); Swift Dec. at ¶ 56. The USP is well-known to POSAs as an authoritative treatise on many topics in pharmaceutical sciences, including X-ray diffraction testing. Swift Dec. at ¶¶ 56, 72.

Each X-ray diffraction pattern (or diffractogram) of a particular polymorph of a compound will exhibit a particular set of peaks and peak intensities, often referred to as a "fingerprint." *Id.* at ¶ 56. An API of moderate size will typically have dozens of peaks in its XRD pattern. *Id.* The absolute peak intensities may vary considerably due to sample orientation and/or the morphology of crystals, depending on how one produces, formulates, and/or tablets the crystalline material. *Id.* at ¶¶ 58-59.

USP 941 discloses that "[t]he agreement in the 2θ-diffraction angles between specimen and reference is within 0.2° for the same crystal form, while relative intensities between specimen and reference may vary considerably due to preferred orientation effects." Ex. K, USP 941 at 507. Moreover, "[i]n addition to the diffraction peaks, an X-ray diffraction experiment also generates a more or less uniform background, upon which the peaks are superimposed. Besides specimen preparation, other factors contribute to the background—for example, sample holder, diffuse scattering from air and equipment, and other instrumental parameters such as detector noise and general radiation from the X-ray tube." *Id*. at 504.

According to Dr. Swift, the POSA for the Patents-in-Suit is a scientist with a degree in pharmaceutical science, chemistry, or chemical engineering, and/or materials sciences with the working knowledge of the theory and practice of crystallography, crystal engineering, and pharmaceutical solid state chemistry, including polymorph, salt, and/or co-crystal screening, characterization, and

development. Swift Dec. at ¶ 31. Dr. Swift also opines that the POSA could have a Ph.D. or Master's degree, but a Bachelor's degree in these disciplines coupled with at least five years of practical experience in the field of pharmaceutical solid state chemistry is also sufficient. *Id.* Further, Dr. Swift opines that the POSA may also work in collaboration with others having pharmaceutical formulation, drug development and/or medicinal chemistry experience. *See id.*

III. LEGAL STANDARDS

The claims of a patent define the scope of the invention. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996). The interpretation of claim language is a question of law for the court to decide. *Id.* at 391. Claim terms should be given their ordinary and customary meaning as understood by a POSA at the time of the invention. *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 884 (Fed. Cir. 2008) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-14 (Fed. Cir. 2005) (en banc)). Moreover, "[i]n some cases, the ordinary meaning of claim language as understood by a [POSA] may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. A party seeking "to alter the meaning of a clear claim term must overcome the presumption that the ordinary and accustomed meaning is the proper one," and must demonstrate "why such an alteration is required." *K-2 Corp. v. Salomon S.A.*, 191

F.3d 1356, 1363 (Fed. Cir. 1999). Claim terms are therefore given their plain and ordinary meaning absent a compelling reason for departure. *See Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) ("Claim terms are generally given their plain and ordinary meanings to one of skill in the art when read in the context of the specification and prosecution history.").

Claims are to be interpreted in view of the intrinsic record: the claim language, the specification, and the prosecution history. *Phillips*, 415 F.3d at 1314; *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). "The claim construction inquiry . . . begins and ends in all cases with the actual words of the claim." *Homeland Housewares, LLC v. Whirlpool Corp.*, 865 F.3d 1372, 1375 (Fed. Cir. 2017) (internal quotation marks and citation omitted). "[T]he context in which a term is used in the asserted claim can be highly instructive." *Phillips*, 415 F.3d at 1314.

Even though the claims themselves define the scope of the patent, the specification "is the single best guide to the meaning of a disputed term." *Vitronics*, 90 F.3d at 1582; *Phillips*, 415 F.3d at 1315. "[I]t is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1153 (Fed. Cir. 1997) (quoting *Vitronics*, 90 F.3d at 1582). A patent

applicant "may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition is clearly stated in the patent specification or file history." *Vitronics*, 90 F.3d at 1582.

Courts also may consider extrinsic evidence, i.e., any evidence other than the patent and its prosecution history, such as expert testimony, inventor testimony, dictionaries, and technical treatises and articles. Extrinsic evidence, however, may not contradict the intrinsic evidence, *Vitronics*, 90 F.3d at 1584; *see also Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 996 (Fed. Cir. 2006), and is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (citation omitted).

Negative limitations, or those that exclude a particular element, "must find support either in 'the words of the claim' or through an 'express disclaimer or independent lexicography in the written description that would justify adding that negative limitation.'" *Ethicon LLC v. Intuitive Surgical, Inc.*, 847 Fed. Appx. 901, 907 (Fed. Cir. 2021) (quoting *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003)). The Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment," *Phillips*, 415 F.3d at 1323, and that principle "is especially true" where a "proposed construction includes a negative limitation." *Ethicon*, 847 Fed. Appx. at 907.

IV. ANALYSIS OF THE DISPUTED CLAIM TERMS

For all the reasons discussed below, a POSA as of March 31, 2014, the effective filing date of the '099 patent, would have understood the disputed claim terms to have the meanings Curia proposes.

A. "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" in claim 1 of the '099 patent

Claim Term for Construction	Curia's Proposed Construction	Defendants' Proposed Construction
"a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" '099 patent claim 1	Construction of "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" is not necessary. To the extent construction is necessary, "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" is meant to have its plain and ordinary meaning, e.g., "any Rifaximin polymorphic mixture that comprises both the α and β forms of Rifaximin." The term "comprises" is open ended and its plain and ordinary meaning allows for inclusion of other rifaximin polymorphs.	"A rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs and no other Rifaximin polymorphs"

1. Curia's construction of "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" as its plain and ordinary meaning is consistent with and supported by the intrinsic evidence.

The plain and ordinary meaning of the claim term "a Rifaximin polymorphic

mixture that comprises α and β Rifaximin polymorphs" is "any Rifaximin polymorphic mixture that comprises both the α and β forms of Rifaximin." This construction is consistent with the claim language and the intrinsic record, which make clear that the claims may encompass any rifaximin composition, including mixtures with other polymorphic forms of rifaximin in addition to the α and β forms.

In the prior claim construction ruling, this Court construed "[a] rifaximin polymorphic mixture of α/β form" in the '915 and '257 patents to mean "[a] rifaximin polymorphic mixture of α/β form which contains no other rifaximin polymorphs," because although the term "mixture" "leaves open the possibility that the disputed terms ***may*** encompass additional rifaximin polymorphs, the specifications here clearly preclude such a possibility." D.I. 210 at 45, 54 (emphasis added).

Unlike the '915 and '257 patent claims, the claim language in the '099 patent, while having some similarities to the previously construed claim phrase, differs in a significant way. *See Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed. Cir. 1999) ("different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope"); *In re Rambus Inc.*, 694 F.3d 42, 48 (Fed. Cir. 2012) (claim differentiation supported broader construction of claim term in patent compared to related patent claims). The inclusion of "comprising" as the transitional phrase and the word "comprises" in

defining the claimed mixture leaves no ambiguity as to the "open-ended" nature of the claim. This added clarity as to the open-ended nature of the claimed mixture overcomes the Court's prior concerns regarding the statements in the patent specification. As the Court noted, "there is a fine line between construing the Claims in light of the specifications and improperly importing limitations from the specifications into the Claims" (D.I. 210 at 54), and the specification of the '099 patent would not alter the "open-ended" nature of the claims of the '099 patent. *See Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1287 (Fed. Cir. 2010) ("Construing the claims in light of the specification does not [] imply that limitations discussed in the specification may be read into the claims.").

"It is elementary that claim construction begins with, and remains focused on, the language of the claims." *Biagro Western Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1302 (Fed. Cir. 2005). The claim language of the '099 patent defining the mixture uses both the words "comprising" and "comprises." Such wording and context unambiguously support Curia's open-ended construction. Claim 1, in which the disputed term appears, consistently uses the terms "comprising," and "comprises," which are well-known to connote that the claims are open-ended to inclusion of other components in the mixture. Other claim language additionally signals the open-endedness of the claims, namely the other open-ended terms "mixture," and "relative ratio":

> 1. A tablet obtained by a dry granulation and tableting procedure *comprising a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs in a α/β relative ratio* of 85/15±3, wherein the Rifaximin polymorphic mixture is characterized by an X-Ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

Ex. C, '099 patent at claim 1 (emphasis added). Most instructive, it is black letter law that the transitional phrases "comprising" and "comprises" are "inclusive or open-ended and do[] not exclude additional, unrecited elements or method steps," such as polymorphic forms of rifaximin in addition to the α and β forms. MPEP, 8th ed., rev. 1 § 2111.03 (2003); *see also* MPEP, 9th ed., rev. 10 § 211.03 (2019); *Mars, Inc. v. H.J. Heinz Co., L.P.*, 377 F.3d 1369, 1375-76 (Fed. Cir. 2004) (quoting the MPEP's definition of "comprising"); *In re Qapsule Techs., Inc.*, 759 Fed. Appx. 975, 980 (Fed. Cir. 2019) ("the whole of the claimed 'synthetic capsule construct' is offset by the 'comprising' transitional, signaling the intent to have an open-ended claim that would allow for additional, unrecited elements").

The terms "*mixture*" and "*relative ratio*" in the '099 patent claims provide additional context that the claim is open-ended. Like "comprising," the term "mixture" is an open-ended term that allows for inclusion of additional ingredients and does not exclude additional, unrecited elements such as rifaximin polymorphs in addition to α and β. *See Mars*, 377 F.3d at 1375-76 ("[L]ike the term 'comprising,' the term[] . . . 'mixture' [is] open-ended." "There is nothing within the ordinary

meaning of 'mixture' that bars additional, unnamed ingredients."); *see also* D.I. 210 at 16.

Moreover, the patentees' use of the term "relative" also supports Curia's open-ended construction. To exclude from the claim construction mixtures comprising rifaximin polymorphs other than the α and β forms would impermissibly render the inclusion of the term "relative" superfluous, especially since "comprising" and "comprises" are also used in the claim. *See Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (construing claim term so as not to "render other parts of the claim superfluous" and stating "A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."). "Relative" refers to the relation between the α and β rifaximin polymorphs, and its use would not be necessary if forms other than α and β had been excluded from the claims. Rather, the inclusion of "relative" conveys to a POSA that rifaximin polymorphs other than the α and β forms are intended to be covered by the claims as long as the ratio of the α:β polymorphs falls within the 85/15±3 range. *See* Swift Dec. at ¶ 84. Therefore, in addition to the terms "comprising" and "comprises," the use of "mixture" and "relative ratio" in the claims would have led a POSA to understand that the claims allow for inclusion of rifaximin polymorphs in addition to the α and β forms. *See, e.g.*, Swift Dec. at ¶¶ 84-85.

A POSA also would have understood from the patent specification that the

claimed invention allows for other polymorphs in the claimed rifaximin polymorphic mixture. First, the specification references a multitude of additional rifaximin polymorphs, including from Defendants' own disclosures:

> α, β, and γ forms were disclosed on 2004 ([] by Alfa Wasserman), the ε and δ forms on 2006 ([] by Alfa Wasserman), the ζ, η, α dry, forms on 2009 ([] by Salix Pharmaceuticals, Ltd.), κ and θ forms on 2011 ([] by Salix Pharmaceuticals, Ltd.).

Ex. C, '099 patent at 1:61-2:1. Prior art cited on the face of the '099 patent also discloses other polymorphic forms of rifaximin. *See V-Formation, Inc. v. Benetton Grp. SpA*, 401 F.3d 1307, 1311 (Fed. Cir. 2005) ("The district court properly considered other intrinsic evidence ["prior art that was listed as a reference on the face of the [] patent and in an Information Disclosure Statement"] to aid its construction."). This cited prior art disclosing additional rifaximin forms includes patents that Defendants own. *See* Ex. L, U.S. Patent No. 7,612,199 ("the '199 patent") at claims 1, 4, 6 (disclosing rifaximin polymorphic forms α, β, and γ); Ex. M, U.S. Patent No. 8,193,196 ("the '196 patent") at claim 1 (disclosing rifaximin polymorphic forms δ and ε); Ex. N, U.S. Patent No. 8,486,956 ("the '956 patent") at claims 1, 4 (disclosing rifaximin polymorphic forms ζ and ι).

In defining the claimed invention, the '099 patent specification also includes both broad and narrower recitations of the inventions. For example, the specification broadly states that "it is an object of the present invention a Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3," and "[a]nother object of the

present inventions is a process for the preparation of said Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3." Ex. C, '099 patent at 3:24-29; *see also id.* at 3:30-54. These statements are in stark contrast to other narrower statements of the inventions that include language such as "can be prepared consistently solving the problems of the prior art" and "a *consistent* Rifaximin α/β mixture in a relative ratio of 85/15±3." *Id.* at 3-18 (emphasis added). The claims themselves do not include the limiting language of the narrow recitations of the inventions. Thus, a POSA would not consider the wording of the '099 claims to be limited to mixtures having only α and β polymorphic forms of rifaximin.

Therefore, as a whole, the intrinsic evidence is consistent with and supports Curia's construction.

2. Defendants' proposed construction improperly adds unfounded negative limitations.

Defendants' proposed claim construction for the claim term "a rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" improperly attempts to add negative limitations to the claim for which there is no support. *Ethicon*, 847 Fed. Appx. at 907 (negative limitations, or those that exclude a particular element, "must find support either in 'the words of the claim' or through an 'express disclaimer or independent lexicography in the written description that would justify adding that negative limitation.'") (quoting *Omega Eng'g*, 334 F.3d at 1323). As explained above, the scope of the patent claim encompasses polymorphic

forms of rifaximin in addition to the α and β forms. *See Ethicon*, 847 Fed. Appx. at 908 (finding "no basis in the intrinsic evidence for importing" negative limitation into claim). Nothing in the '099 claims, specification, or prosecution history would have led a POSA to understand that additional rifaximin polymorphs should be excluded from the claim scope. And the extrinsic evidence does not support exclusion either.

Defendants' proposed claim construction would vitiate the patentees' use of both "comprising" and "comprises" as open-ended transitional phrases in the claim. A POSA would have understood that the use of the terms "comprising" and "comprises" as the transitional phrases is interpreted as open-ended. *See Sonoco Products Co. v. Mobil Oil Corp.*, 895 F.2d 1420, 1420 (Fed. Cir. 1990) (emphasizing effect of transitional phrase used on claim scope breadth). Defendants' proposed claim construction would also vitiate the use of the terms "mixture" and "relative ratio" in the claim.

Curia will respond in its response claim construction brief to any portion of the prosecution history that Defendants claim warrants a disavowal of claim scope, but the evidence generally cited by Defendants in the parties' joint claim construction and prehearing statement (D.I. 216) does not call for exclusion, let alone meet the "exacting" standard of prosecution disclaimer or exclusion of additional rifaximin polymorphs. *See Luminara Worldwide, LLC v. Liown Elecs.*

Co. Ltd., 814 F.3d 1343, 1353 (Fed. Cir. 2016) ("disavowal requires that 'the specification [or prosecution history] make[] clear that the invention does not include a particular feature.'") (internal citations omitted) (alterations in original).

Given the unambiguous intrinsic evidence that the claims can comprise other rifaximin polymorphs in addition to α and β, there is no reason, nor would it be proper for the Court to rewrite the claims to exclude other rifaximin polymorphs. *See Chamberlain Group, Inc. v. Lear Corp.*, 516 F.3d 1331, 1339 (Fed. Cir. 2008) (rejecting district court's claim construction because it was "internally inconsistent and contradictory to the rest of the patent"); *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1362 (Fed. Cir. 2002) (rejecting district court's claim construction that improperly narrowed disputed claim term because the claim term "has an established meaning and because nothing in the intrinsic evidence narrows that claim term's ordinary meaning").

3. Extrinsic evidence, while unnecessary, additionally supports Curia's construction.

Because the intrinsic evidence unambiguously resolves the dispute as to the meaning of the claim term, it is unnecessary to rely on extrinsic evidence here. However, Curia submits Dr. Swift's declaration for the Court's consideration in construing the disputed terms. *See Phillips*, 415 F.3d at 1318 ("We have also held that extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology at issue, to

explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field."). Dr. Swift confirms that Curia's construction is consistent with how a POSA would have understood the meaning of the claim considering the '099 patent as a whole at the relevant time period. Swift Dec. at ¶¶ 80-91. And the Court may rely on Dr. Swift's testimony as it is entirely consistent with the intrinsic evidence discussed above. *See Phillips*, 415 F.3d at 1318.

B. "characterized by an X-Ray spectrum with characteristic 2theta values" in claim 1 of the '099 patent

Claim Term for Construction	Curia's Proposed Construction	Defendants' Proposed Construction
"characterized by an X-Ray spectrum with characteristic 2theta values" '099 patent claim 1	Read in the context of the claim and specification as a whole, this phrase means: "characterized by an X-Ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92."	"having an X-ray spectrum with peaks at each of the recited 2theta values"

1. The intrinsic evidence supports and is consistent with Curia's construction.

"The claim construction inquiry . . . begins and ends in all cases with the actual words of the claim." *Homeland Housewares, LLC v. Whirlpool Corp.*, 865 F.3d

1372, 1375 (Fed. Cir. 2017) (internal quotation marks and citation omitted). The disputed claim term in the context of the claim reads:

> 1. A tablet obtained by a dry granulation and tableting procedure comprising a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs in a α/β relative ratio of 85/15±3, wherein the Rifaximin polymorphic mixture is *characterized by an X-Ray spectrum with characteristic 2theta values* at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

The phrases "characterized by" and "characteristic" in this claim term are dispositive and dictate against Defendants' proposed construction that would always require each and every recited 2theta value.

The plain and ordinary meaning of "characterized by" and "characteristic" means to be able to identify something and "does not require all of the recited [2theta values] to be present in every experimental run (i.e., an exact one-to-one match)." *Eisai Co. v. Glenmark Pharms., Ltd.*, C.A. No. 13-1279-LPS, 2015 WL 1228958, at *8 (D. Del. March 17, 2015) (holding that "the claim limitation is satisfied as long as the crystal form can be 'characterized by' – that is, **identified by** – reference to **the characteristic lines** set forth in the claim" for interplanar spacings (d values) from XRPD) (emphasis in original).

The '099 patent specification further clarifies that a POSA need not consider values to be absolute as long as the "technical effect herein disclosed is achieved":

> It is understood that all the values and intervals disclosed in the process of the present invention must not be intended as absolute. Any value

> or interval must be understood by the person of ordinary skill in the art as "about". The term "about", as currently intended, means that any value herein disclosed not necessarily must be exactly taken per se, but that a deviation from this value is within the scope of the present invention, provided that the technical effect herein disclosed is achieved.

Ex. C, '099 patent at 4:62-5:3. A POSA would understand that the *technical effect* of the '099 patent would be achieved if a POSA could obtain and identify a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs in a α/β relative ratio of 85/15±3 using an X-Ray spectrum with characteristic 2theta values. *See* Swift Dec. at ¶ 65. The limitations of claim 1 of the '099 patent would be satisfied if a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs in a α/β relative ratio of 85/15±3 can be identified in the substance in question by reference to the X-Ray spectrum characterized by the characteristic 2theta values set forth in claim 1 of the '099 patent. *Id.* at ¶ 66. Nothing in the '099 patent or the prosecution history supports Defendants attempt to change the claim term "characteristic" to the phrase "at each of the recited" in their proposed construction of "having an X-ray spectrum with peaks at each of the recited 2theta values."[3]

[3] Even though the terms "characterized by" and "characteristic" were present in the claims of the '915, '415, and '257 patents which this Court previously held *Markman* proceedings for, Defendants did not raise any need to construe such terms in those patents even though the language is substantially the same in claim 1 of the '099 patent. Curia believes Defendants' failure to previously raise this at claim construction should operate as a waiver.

2. Extrinsic evidence, while unnecessary, additionally supports Curia's construction.

Again, given the clarity of the intrinsic evidence, extrinsic evidence is unnecessary. Nevertheless, extrinsic evidence is useful for construing this term. Dr. Swift confirms that Curia's construction is consistent with how a POSA would have understood the meaning of the claim considering the '099 patent as a whole at the relevant time period. Swift Dec. at ¶¶ 64-79. Dr. Swift explains that a POSA would recognize that, due to various factors, not all known 2theta values may be detected all the time. *Id.* at ¶ 72.

USP is an authoritative guide, and a POSA would have looked specifically to USP 941 that discloses that "[t]he identification of the phase composition of an unknown sample by XRPD is usually based on the visual or computer-assisted comparison of a portion of its X-ray powder pattern to the experimental or calculated pattern of a reference material." Ex. K, USP 941 at 507; Swift Dec. at ¶¶ 71-72. USP 941 also discloses that "relative intensities between specimen and reference may vary considerably due to preferred orientation effects." *Id.* This fact would lead a POSA to recognize that some of the 2theta values may not always be detectable. *Id.*

Further, as of the priority date of the '099 patent, a POSA would have also been well aware of what is referred to as "background" which is x-ray scattering caused by something other than the sample at issue. The X-ray diffraction

equipment itself contributes to background, as well as excipients in the drug product, specimen preparation, the "sample holder, diffuse scattering from air and equipment, and other instrumental parameters such as detector noise and general radiation from the X-ray tube." Ex. K, USP 941 at 504; Swift Dec. at ¶¶ 73, 76. A POSA would know that the background from any of these sources could superimpose with certain diffraction peaks and cause them to be undetected. *Id.* For instance, a background peak could add to a claimed peak, widening and shifting the combined peak. In this way, the combined peak may mask the peak of interest. Therefore, given the realities of XRD technology, a POSA would not interpret the claim to be so rigid as to require each and every one of the 18 peaks identified to characterize the invention.

3. Defendants' proposed construction impermissibly narrows the scope of the claim.

Defendants' proposed construction changing and importing words into the claim language to require "an X-ray spectrum with peaks at each of the recited 2theta values" would impermissibly narrow the scope of claim 1, which leaves open the possibility for variability in detected peaks—such as missing one of the recited diffraction peaks in claim 1.

Defendants' proposed construction ignores the knowledge of a POSA as described in the previous section. This point is illustrated by the '099 patent specification, which discloses that the polymorphic mixtures can be in the form of pharmaceutical compositions containing excipients. Some of these excipients that

may be present have diffraction peaks that are superimposed with the claimed characteristic 2theta values. *See* Ex. C, '099 patent at 7:10-18 (disclosing diffraction peaks of 19.10 and 28.72 for talc; 22.36 for microcrystalline cellulose; and 21.10 for glycerol palmitostearate). A POSA would understand that the overlapping peaks (*e.g.*, 21.10 2theta for glycerol palmitostearate and 21.04 2theta in claim 1) or adjacent peaks (e.g., 22.36 2theta for microcrystalline cellulose and the 21.92 2theta in claim 1) could alter the background upon which the peaks are superimposed, and as a result, potentially change the characteristic 2theta values, which may also lead to some of the diffraction peaks not being detected. *See* Swift Dec. at ¶ 76.

In contrast to Defendants' proposed construction, Curia proposes that the construction of the "characterized by" term be consistent with how a POSA would confirm whether a claimed polymorphic mixture in a specific ratio is present or absent—that is, a POSA would review the X-Ray diffraction pattern as a whole, referencing the recited diffraction values, and conduct a computer-assisted comparison to confirm the presence or absence of the claimed subject matter (here, a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs in a α/β relative ratio of 85/15±3). *See id.* A POSA would not need to "see" all of the recited peaks to make this determination.

Defendants' own patents support Curia's construction. These patents, the '199, '196, and '956 patents (Exhibits L, M, and N, respectively) cited on the face

of the '099 patent (therefore qualifying as intrinsic evidence under *V-Formation, Inc.*, 401 F.3d at 1311) are directed to polymorphic forms of rifaximin and characterize both the α and β polymorph from only seven (7) total 2theta peaks. *See, e.g.*, Ex. L, the '199 patent at claim 1 (requiring four diffraction peaks at about 7.4°; 19.7°; 21.0° and 22.1° 2θ to characterize rifaximin polymorph α); *id.* at claim 4 (requiring three diffraction peaks at about 5.4°; 9.0°; and 20.9° 2θ to characterize rifaximin polymorph β). These seven (7) total peaks pale in comparison to the eighteen (18) peaks recited in claim 1 of the '099 patent. A POSA would understand from this that a mixture of α and β rifaximin polymorphs can be discerned from less than the eighteen (18) peaks recited in the '099 patent to identify the claimed subject matter (i.e. a rifaximin polymorphic mixture that comprises α and β rifaximin polymorphs in a α/β relative ratio of 85/15±3) and determine that the technical effect is achieved. *See* Swift Dec. at ¶ 68.

Therefore, Defendants' proposed construction departs from not only the intrinsic evidence but also from the extrinsic evidence and the understanding of a POSA. Accordingly, the Court should respectfully adopt Curia's construction which is fully consistent with the intrinsic and extrinsic evidence.

V. CONCLUSION

For the foregoing reasons, Curia respectfully requests that the Court adopt all of Curia's proposed constructions of the disputed terms and reject all of Defendants'

proposed constructions.

Dated: May 22, 2024

/s/ *Eric I. Abraham*

Eric I. Abraham
William Murtha
HILL WALLACK, LLP
21 Roszel Road
Princeton, NJ 08543
Telephone: (609) 924-0808

Of Counsel
Alan B. Clement (*pro hac vice*)
Mark Hannemann (*pro hac vice*)
Zhibin Li
LOCKE LORD LLP
Brookfield Place, 200 Vesey Street
New York, New York 10281
Telephone: 212-415-8600
Facsimile: 212-303-2754

Nina Vachhani (*pro hac vice*)
David M. Knapp (*pro hac vice*)
Leah Brackensick (*pro hac vice*)
LOCKE LORD LLP
111 South Wacker Drive
Chicago, Illinois 60606

Attorneys for Plaintiff Curia IP Holdings, LLC